Drug approvals: exclusive Health Canada jurisdiction or fair game for the provinces?

Introduction

In just over four months, a single case of COVID-19 in Wuhan, China spread to nearly 4 million people and caused over 270,000 fatalities, leaving the world desperate for treatments, vaccines, or rapid testing technology to help bring an end to physical distancing. On April 12, Alberta Premier Jason Kenney expressed frustration at a perceived delay in Health Canada's drug and device approval times, stating on Twitter that "I have directed our officials to consider use of COVID19 tests, vaccines, or medications that have been approved by the high standards of at least one credible peer country's drug agency… We won't wait for Health Canada to play catch up."[1]

On April 20, we published an op-ed in the Globe and Mail that questioned the constitutional legitimacy and wisdom of bypassing Health Canada.[2] One common reaction to the op-ed was that Mr. Kenney is standing up for Albertans by putting our interests above everything else, especially in the face of what some see as catastrophic and contradictory federal handling of the pandemic. This type of reaction suggests that to some, when it comes to a public health crisis, federalism encumbers provincial interests. We take the opposite view and believe that cooperative federalism is crucial during a pandemic. In particular, we argue that the proposal to do an end-run around Health Canada's drug and device approval process raises a host of constitutional and practical problems and could jeopardize the health of Canadians.

Constitutional Jurisdiction and Drug Regulation

The Constitution does not assign jurisdiction over "health" to either the provinces or the federal government. As Justice Estey put it in *Schneider v The Queen*, health "is not a matter which is subject to specific constitutional assignment but instead is an amorphous topic which can be addressed by valid federal or provincial legislation, depending in the circumstances of each case on the nature or scope of the health problem in question."[3]

The federal power to regulate in relation to the criminal law is most relevant to health-related matters and has been interpreted broadly to include public health issues like safe injection sites,[4] food safety,[5] reproductive technologies,[6] and tobacco control.[7] In *RJR MacDonald v Canada (Attorney General)*, Justice LaForest stated that "[t]he scope of the federal power to create criminal legislation with respect to health matters is broad, and is circumscribed only by the requirements that the legislation must contain a prohibition

accompanied by a penal sanction and must be directed at a legitimate public health evil."[8] Pursuant to the criminal law power, the federal government has been regulating health products through the *Food and Drugs Act* for over 100 years. In *R v Wetmore*, the Supreme Court of Canada addressed this legislation, stating that "it has been well understood over many years that the protection of food and other products against adulteration and to enforce standards of purity are properly assigned to the criminal law."[9]

According to the Supreme Court of Canada, the provinces have "jurisdiction over health care in the province generally, including matters of cost and efficiency, the nature of the health care delivery system, and privatization of the provision of medical services."[10] Several provincial heads of power are relevant to public health, including the power to regulate hospitals, property and civil rights, and matters of a merely local or private nature. These powers have resulted in provinces regulating the delivery and insurance of health care services and the regulation of health facilities and health professionals. Although these powers certainly encompass things like the provision of a public drug benefit plan and the regulation of pharmacists and pharmacies, they are not as clearly relevant to drug approvals as the federal criminal law power.

Even if the federal government and the provinces could both regulate in this space, any conflict would be resolved in favour of the federal government in accordance with the paramountcy doctrine.[11] Constitutional technicalities aside, provincial incursion into drug regulation would disrupt Canada's complex healthcare system, which hinges on cooperation between the two levels of government.

Safety Concerns and Practical Issues with Provincial Drug Approvals

History has taught us that relaxed or inefficient regulation can produce disastrous consequences, as with thalidomide in the 1960s, which resulted in an estimated 24,000 babies born with congenital defects and 123,000 stillbirths and miscarriages.[12] Undue haste in finding a cure or treatment for COVID-19 has produced similarly concerning results. For example, optimistic projections based on dubious evidence about the benefits of hydroxychloroquine as a COVID-19 treatment, including by U.S. President Donald Trump, fizzled after clinical trials reported no positive outcomes. Preliminary results suggest that hydroxychloroquine does not reduce the risk of mechanical ventilation in patients hospitalized with COVID-19[13] and thus its benefits may not be worth potentially serious cardiac side effects.[14] Similarly, Japan's Prime Minister Shinzo Abe, became a vocal proponent of an antiviral medication called Avigan despite the lack of solid evidence that Avigan provides an effective treatment for COVID-19. Avigan has also been associated with birth defects.[15]

The hasty adoption of medical technologies can also be costly. For example, in late March, Alberta Health Services announced a partnership worth $9.5 million with Spartan Biosciences, the company behind a rapid coronavirus test. Subsequently, the test was recalled after Health Canada expressed concerns that components of the test were not effective.[16]

The notion that Alberta should create a parallel drug approval process for the purpose of rapidly gaining access to COVID-19 treatments and tests is part of a dangerous trend that emphasizes approval speed over safety and efficacy. This trend has led to a huge exploitative market for unproven therapies, many of which rely on falsehoods and half-truths such as claims that the public would be better served by a system that makes products available quicker, despite a lack of scientific evidence. But studies show good science takes time, and that around 90 percent of drugs tested in clinical trials fail to obtain market approval.[17] Although some unsafe or ineffective products still make it to market, there would be many more if the approval system were less rigorous.

Federal regulations do make allowances for expedited approvals of drugs. For example, Canada can approve a drug with incomplete safety or efficacy data, conditional upon manufacturers continuing to study the product post-approval. Eligibility for this program is restricted to promising new drugs intended for the treatment of serious conditions for which there are no available therapies, or drugs that are a significant improvement over existing ones.[18] The federal government has also announced specific initiatives related to COVID-19. For example, Health Canada issued a notice that it will expedite the review process for products that address the disease.[19] Still, it is essential that expedited approvals are used with caution, given studies showing that drugs approved on an expedited basis were linked to more safety warnings than drugs approved through regular channels.[20]

In addition to safety concerns, the proposal for parallel provincial drug approval processes raises financial and logistical problems. Drug and device approvals are an expensive and exceedingly complex process that requires significant expertise and detailed regulatory procedures. It would be costly and highly inefficient for provinces to duplicate one another's efforts with individual parallel regulatory processes. If drugs had to pass through multiple approval processes, this would also be likely to drive up the cost of drugs. Furthermore, drugs are imported into Canada pursuant to federal authorization, so it is unclear whether Alberta could even import drugs or devices that it had approved, unless those products were already manufactured or could be manufactured in Canada.

Conclusion

If there were genuine concerns with drug or device approval times, Alberta should work with federal regulators instead of sending inflammatory tweets that undermine the public's trust in Health Canada, which is essential during a pandemic. It is also inappropriate to politicize what must be a science-focused approval process, given that hasty approvals may raise serious safety concerns. Furthermore, Alberta's plan to usurp the regulation of medical devices, drugs, and vaccines is constitutionally suspect and logistically problematic.

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[1] Janet French, "Alberta may circumvent Health Canada to gain access to COVID-19 tests and drugs, premier says", online: CBC <https://www.cbc.ca/news/canada/edmonton/kenney-covid-19-test-coronavirus-health-canada-dr-theresa-tam-1.5531175>.

[2] Ubaka Ogbogu & Lorian Hardcastle, "Crisis or not, Alberta must not do an end-run around Health Canada", *The Globe and Mail* (20 April 2020), online: <https://www.theglobeandmail.com/opinion/article-crisis-or-not-alberta-must-not-do-an-end-run-around-health-canada/>.

[3] [1982] 2 SCR 112 at 142, 139 DLR (3d) 417.

[4] *Canada (Attorney General) v PHS Community Services Society*, 2011 SCC 44.

[5] *Standard Sausage Company v Lee*, [1934] 1 DLR 706, 1 WWR 81.

[6] *Reference re Assisted Human Reproduction Act*, 2010 SCC 61. For a discussion of the criminal law power in this case, see e.g. Ubaka Ogbogu, "The *Assisted Human Reproduction Act* and the Thin Line Between Health and Crime" (2013) 22:1 Constitutional Forum 93.

[7] [1995] 3 SCR 199, 127 DLR (4th) 1.

[8] *Ibid* at 246.

[9] [1983] 2 SCR 284 at 288, 2 DLR (4th) 577.

[10] *R v Morgentaler*, [1993] 3 SCR 463 at 491, 107 DLR (4th) 537.

[11] As the Supreme Court of Canada stated in *Rothmans, Benson & Hedges Inc v Saskatchewan*, 2005 SCC 13 at para 11, "where there is an inconsistency between validly enacted but overlapping provincial and federal legislation, the provincial legislation is inoperative to the extent of the inconsistency."

[12] Daniel Schwartz, "Thalidomide disaster: background to the compensation debate", online: CBC <https://www.cbc.ca/news/health/thalidomide-explainer-1.4434746>.

[13] Joseph Magagnoli et al, "Outcomes of hydroxychloroquine usage in United States veterans hospitalized with Covid-19", online: medRxiv <https://www.medrxiv.org/content/10.1101/2020.04.16.20065920v1.full.pdf>.

[14] Katie Thomas & Knvul Sheikh, "Small Chloroquine Study Halted Over Risk of Fatal Heart Complications", *The New York Times* (12 April 2020), online: <https://www.nytimes.com/2020/04/12/health/chloroquine-coronavirus-trump.html>.

[15] Ben Dooley, "This Drug May Cause Birth Defects: Japan's Pushing It for Coronavirus", *The New York Times* (5 May 2020), online: <https://www.nytimes.com/2020/05/05/business/japan-avigan-coronavirus.html>.

[16] Allison Bench, “Recall issued for rapid coronavirus test with $9.5M Alberta Health Services Contract”, online: Global News <https://globalnews.ca/news/6899733/spartan-covid-19-recall-ahs-testing/>.

[17] Chi Heem Wong, Kien Ei Siah & Andrew W Lo, “Estimation of clinical trial success rates and related parameters” (2018) 20:2 Biostatistics 273.

[18] Health Canada, “Notice of Compliance with Conditions—NOC/c (Therapeutic Products”, online: <https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/noccfs_accfd-eng.pdf>.

[19] Health Canada, “Notice: Expedited Review of Health Product Submissions and Applications to address COVID-19”, online: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/notice-expediated-review-health-products-covid-19.html>.

[20] Joel Lexchin, “Post-market safety warnings for drugs approved in Canada under the Notice of Compliance with conditions policy” (2014) 79:5 Br J Clin Pharmacol 847.